IFU

Instructions for Use

CRITERION™ TAT BROTH BASE

Cat. no. C7030	CRITERION™ TAT Broth Base	56gm
Cat. no. C7031	CRITERION™ TAT Broth Base	500gm
Cat. no. C7032	CRITERION™ TAT Broth Base	2kg
Cat. no. C7033	CRITERION™ TAT Broth Base	10kg
Cat. no. C7034	CRITERION™ TAT Broth Base	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ TAT Broth Base is used for cultivating microorganisms from highly viscous or gelatinous materials.

This dehydrated culture medium is a raw material intended to be used in the making of prepared media products, which will require further processing, additional ingredients, or supplements.

SUMMARY

TAT (Trypton-Azolectin-Tween®) Broth is recommended for sterility testing of viscous materials, such as salves or ointments. It is especially adapted to the sterility testing of cosmetics. Cosmetics and pharmaceutical products are subject to contamination during manufacturing and use by consumers.[7] Preservatives are used in aqueous products to make them self-sterilizing for vegetative bacteria, yeasts, and molds.

CRITERION™ TAT Broth Base is an enrichment medium developed to isolate and cultivate microorganisms. CRITERION™ TAT Broth Base conforms to the formula specified by U.S. Pharmacopeia for use in Microbial Limit Tests.[6]

Pancreatic digest of casein provides the nitrogen, vitamins, amino acids, and carbon in CRITERION™ TAT Broth Base. Lecithin (azolectin) neutralizes preservatives in the cosmetics or pharmaceutical products, allowing bacteria to grow.

FORMULA

Gram weight per liter:	28.0gm/L
Pancreatic Digest of Casein	23.0gm
Lecithin	5.0gm

Final pH 7.2 +/- 0.2 at 25ºC.

* Adjusted and/or supplemented as required to meet performance criteria.

STORAGE AND SHELF LIFE

Store the sealed bottle(s) containing dehydrated culture medium at 2-30ºC. Dehydrated culture medium is very hygroscopic. Keep lid tightly sealed. Protect dehydrated culture media from moisture and light. The dehydrated culture media should be discarded if it is not free-flowing or if the color has changed from its original off-white.

Store the prepared culture media at 2-30ºC.

The expiration date on the product label applies to the product in its intact packaging when stored as directed. The product may be used and tested up to the expiration date on the product label and incubated for the recommended incubation times as stated below.

Refer to the document "Storage" for more information.

PRECAUTIONS

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these products be treated as potentially infectious, and handle observing the usual universal blood precautions. Do not ingest, inhale, or allow to come into contact with skin.

This product is for laboratory use only. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." Refer to the document "Guidelines for Isolation Precautions" from the Centers for Disease Control and Prevention.

For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M29: *Protection of Laboratory Workers from Occupationally Acquired Infections.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

METHOD OF PREPARATION FOR DEHYDRATED CULTURE MEDIA

1. Suspend 28.0gm of the dehydrated culture media in 960ml of distilled or deionized water.

2. Add 40ml of Tween® 20.

3. Heat to 50-60ºC.

4. Let stand 15-30 minutes with occasional agitation to dissolve completely.

5. Autoclave at 121ºC. for 15 minutes.

6. Dispense as desired into sterile containers.

PROCEDURE AND INTERPRETATION OF RESULTS

For information on procedures and interpretation of results, consult listed references or refer to the prepared media Instructions for Use (IFU) for Cat. No. K251.

LIMITATIONS

It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies from pure culture for complete identification.

Some formulations may require a settling period before pH testing of the prepared medium. If the pH is tested immediately after preparation and is out of specification, retest the medium after 24 hours to obtain final pH results. Always take pH reading at room temperature.

Since the nutritional requirements of organisms vary, some strains may be encountered that fail to grow or grow poorly on this medium.

Refer to the document "Limitations of Procedures and Warranty" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as autoclaves, incinerators, incubators, and Tween® 20, etc., are not provided.

QUALITY CONTROL

Hardy Diagnostics tests each lot of commercially manufactured media using appropriate quality control microorganisms and quality specifications as outlined on the Certificate of Analysis (CofA) and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media*. The following microorganisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	
Escherichia coli ATCC® 25922	J	18-48hr	35°C	Aerobic	Growth
Pseudomonas aeruginosa ATCC® 27853	J	18-48hr	35°C	Aerobic	Growth
Staphylococcus aureus ATCC® 25923	J	18-48hr	35°C	Aerobic	Growth

* Refer to the document "Inoculation Procedures for Media QC" for more information.

USER QUALITY CONTROL

Users of dehydrated culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory quality control procedures or regulation, perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction, if applicable. Hardy Diagnostics quality control testing is documented on the certificate of analysis (CofA) available from Hardy Diagnostics Certificate of Analysis website. In addition, refer to the following document "Finished Product Quality Control Procedures," for more information on QC or see the reference(s) for more specific information.

PHYSICAL APPEARANCE

CRITERION™ TAT Broth Base powder should appear homogeneous, free-flowing, and beige in color. The prepared media should appear clear to slightly opalescent, and light amber in color.

REFERENCES

1. Jorgensen., et al. *Manual of Clinical Microbiology*, American Society for Microbiology, Washington, D.C.

2. Tille, P., et al. *Bailey and Scott's Diagnostic Microbiology,* C.V. Mosby Company, St. Louis, MO.

3. Isenberg, H.D. *Clinical Microbiology Procedures Handbook,* Vol. I, II & III. American Society for Microbiology, Washington, D.C.

4. Koneman, E.W., et al. *Color Atlas and Textbook of Diagnostic Microbiology,* J.B. Lippincott Company, Philadelphia, PA.

5. MacFaddin, J.F. 1985. *Media for Isolation, Cultivation, Identification, Maintenance of Bacteria,* Vol. I. Williams & Wilkins, Baltimore, MD.

6. The United States Pharmacopeial Convention. 1995. *The United States Pharmacopeia,* 23rd ed. Microbial Test Limits, p. 1681-1686. The United States Pharmacopeial Convention, Inc. Rockville, MD.

7. Orth, D.S. 1993. Handbook of cosmetic microbiology. Marcel Dekker, Inc. New York, NY.

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California · Washington · Utah · Arizona · Texas · Ohio · New York · Florida · North Carolina

The Hardy Diagnostics manufacturing facility and quality management system is certified to ISO 13485.

HDQA 2207B [D]